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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/525,364

09/22/2005

Arun Kumar Dhar

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MOORE & VAN ALLEN PLLC
P.O. BOX 13706
Research Triangle Park, NC 27709

EXAMINER

DEVI, SARVAMANGALA J N

ART UNIT

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1645

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/525,364	Applicant(s) DHAR ET AL.	
	Examiner S. Devi, Ph.D.	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 September 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,5-10,12,17-26 and 32-38 is/are pending in the application.
- 4a) Of the above claim(s) 1, 5-10, 12 and 35-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17-26 and 32-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Request for Continued Examination

1) A request for continued examination under 37 C.F.R. 1.114, including the fee set forth in 37 C.F.R. 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 C.F.R. 1.114, and the fee set forth in 37 C.F.R. 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 C.F.R. 1.114. Applicants' submission filed 09/04/09 has been entered.

Applicants' Amendment

2) Acknowledgment is made of Applicants' amendment filed 09/04/09 in response to the final Office Action mailed 05/14/09.

Status of Claims

3) Claims 1, 12, 17, 18, 21, 24, 34 and 38 have been amended via the amendment filed 09/04/09.

Claims 1, 5-10, 12, 17-26 and 32-38 are pending.

The examination of the species has been extended to cover the VP24, VP26 and VP19 viral protein species.

Claims 17-26 and 32-34 are under examination.

Prior Citation of Title 35 Sections

4) The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office Action.

Prior Citation of References

5) The references cited or used as prior art in support of one or more rejections in the instant Office Action and not included on an attached form PTO-892 or form PTO-1449 have been previously cited and made of record.

Objection(s) Withdrawn

6) The objection to the specification made in paragraph 6 of the Office Action mailed 05/14/09 is withdrawn in light of Applicants' amendment to the claims.

Rejection(s) Withdrawn

- 7)** The rejection of claims 17, 18, 21 and the dependent claims 18-26 and 32-34 made in paragraph 20 of the Office Action mailed 05/14/09 under 35 U.S.C § 112, first paragraph, as containing new matter, is withdrawn in light of Applicants' amendment to the claims and/or the base claim.
- 8)** The rejection of claims 17 and 21 made in paragraphs 22(c) and 22(h) of the Office Action mailed 05/14/09 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claims.
- 9)** The rejection of claim 17 made in paragraphs 22(d) and 22(g) of the Office Action mailed 05/14/09 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.
- 10)** The rejection of claim 21 made in paragraph 22(e) of the Office Action mailed 05/14/09 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.
- 11)** The rejection of claims 18 and 24 made in paragraph 22(f) of the Office Action mailed 05/14/09 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claims.
- 12)** The rejection of claims 17-26, 32 and 33 made in paragraph 24 of the Office Action mailed 05/14/09 under 35 U.S.C. § 102(b) as being anticipated by Kyle *et al.* (US 2004/0047881 A1 - Applicants' IDS), is withdrawn in light of Applicants' amendment to the claims and/or the base claims. A new rejection is set forth below to address the claims as amended.

Rejection(s) Maintained

- 13)** The rejection of claim 18 made in paragraph 7(b) of the Office Action mailed 10/02/08 and maintained in paragraph 15 of the Office Action mailed 05/14/09 under 35 U.S.C. § 112, second paragraph, as being indefinite, is maintained for the reason set forth therein.
- 14)** The rejection of claims 24 and 25 made in paragraph 7(c) of the Office Action mailed 10/02/08 and maintained in paragraph 16 of the Office Action mailed 05/14/09 under 35 U.S.C. § 112, second paragraph, as being indefinite, is maintained for the reason set forth therein.

15) The rejection of claim 23 made in paragraph 7(d) of the Office Action mailed 10/02/08 and maintained in paragraph 17 of the Office Action mailed 05/14/09 under 35 U.S.C. § 112, second paragraph, as being indefinite, is maintained for the reason set forth therein. It is suggested that Applicants replace the above-identified limitation with the limitation --encapsulated purified protein, or encapsulated semi-purified protein--.

16) The rejection of claim 18 made in paragraph 22(a) of the Office Action mailed 05/14/09 under 35 U.S.C. § 112, second paragraph, as being indefinite, is maintained for the reason set forth therein.

17) The rejection of claims 19 and 21-25 made in paragraph 22(b) of the Office Action mailed 05/14/09 under 35 U.S.C. § 112, second paragraph, as being indefinite, is maintained for the reason set forth therein.

18) The rejection of claim 34 made in paragraph 22(i) of the Office Action mailed 05/14/09 under 35 U.S.C. § 112, second paragraph, as being indefinite, is maintained for the reason set forth therein. The claim as amended continues to lack proper antecedent basis in the limitation 'algae'. As set forth previously, claim 34 depends from claim 20, which already includes the pleural limitation 'algae'. For proper antecedent basis, it is suggested again that Applicants replace the above-identified limitation with the limitation --the algae--.

19) The rejection of claims 18-26 and 32-34 made in paragraph 22(j) of the Office Action mailed 05/14/09 under 35 U.S.C. § 112, second paragraph, as being indefinite, is maintained for the reason set forth therein.

Rejection(s) under 35 U.S.C. § 112, Second Paragraph

20) The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude one or more claims particularly pointing out and distinctly claiming the subject matter which the Applicant regards as his/her invention.

21) Claims 17-20, 23-26 and 32-34 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

(a) Claim 17 is indefinite, incorrect and/or confusing in the limitation: 'capable of and blocking' because it is unclear what is it exactly the recited protein or peptide is capable of.

(b) Claim 23 is indefinite because it appears to lack proper antecedent basis in the limitation: 'an animal'. Claim 23 depends from claim 21 which already includes the limitation of 'an animal'. Is 'an animal' recited in claim 23 different from the animal recited in claim 20? If not, it is suggested that Applicants replace the limitation with the limitation --the animal--.

(c) Claim 24 is indefinite because it has improper antecedent basis in the limitation: 'the viral receptor'. Claim 24 depends from claim 21, which includes the plural limitation of --viral receptors--, but not 'viral receptor'.

(d) Claims 18-20 and 32-34, which depend from claim 17, and claims 25 and 26, which depend from claim 24, are also rejected as being indefinite because of the indefiniteness identified above in the base claim.

Rejection(s) under 35 U.S.C. § 102

22) The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language.

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

23) Claims 17-26, 32 and 33 are rejected under 35 U.S.C. § 102(e)(1) as being anticipated by Kyle *et al.* (US 2004/0047881 A1, filed 09/05/03, of record).

Instant claims do not get the effective filing date of the provisional application, i.e., 09/16/02, due to the lack of support therein for the limitation 'TSV capsid protein' recited in the independent claims 17 and 21.

The transitional limitation 'comprising' similar to the limitation, such as, 'having' 'including', 'containing', or 'characterized by', represents open-ended claim language and therefore does not exclude additional, unrecited elements. See M.P.E.P 2111.03 [R-1]. See *Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 229 USPQ 805 (Fed. Cir. 1986); *In re Baxter*, 656 F.2d 679, 686, 210 USPQ 795, 803 (CCPA 1981); *Ex parte Davis*, 80 USPQ 448,

450 (*Bd. App. 1948*) ('comprising' leaves 'the claim open for the inclusion of unspecified ingredients even in major amounts').

Kyle *et al.* disclosed a feed or a feed additive for an animal such as a crustacean shrimp comprising one or more recombinant proteins, peptides, or immunogenic epitopes thereof (i.e., truncated proteins) including VP28, VP24, VP26, or VP19, which inhibit the growth or replication of viral pathogens such as White Spot Syndrome Virus. The protein or the peptide is expressed via transformed host cells of *E. coli* bacteria, algae such as *Chlorella* strains, yeast such as *Saccharomyces*, or other fungi. See abstract; Figure 2; paragraphs [0022], [0024], [0025], [0044], [0047] to [0052] and [0059]; Examples 9, 3 and 4; and claims 1-7, 9, 12, 13, 15, 23, 24, 28-33, 35-39, 52-60, 71, 72, 76-82, 84, 86-88, 92, 93 and 97. The recombinantly produced prior art protein or peptide is at least semi-purified since it does not contain other antigens of White Spot Syndrome Virus. Since the prior art prior art one or more recombinant proteins, peptides, or immunogenic truncated proteins of VP28, VP24, VP26, or VP19 are the same as the Applicants', the capacity to block viral receptors needed for WSSV infection in one or more cells of the animal is viewed as the intrinsic property inseparable from the prior art one or more recombinant proteins, peptides or immunogenic truncated proteins VP28, VP24, VP26, or VP19.

Claims 17-26, 32 and 33 are anticipated by Kyle *et al.*

24) Claims 17-26, 32 and 33 are rejected under 35 U.S.C. § 102(e)(2) as being anticipated by Sayre *et al.* (US 7,410,637, filed 6/20/01).

The transitional limitation 'comprising' similar to the limitation, such as, 'having' 'including', 'containing', or 'characterized by', represents open-ended claim language and therefore does not exclude additional, unrecited elements. See M.P.E.P 2111.03 [R-1]. See *Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 229 USPQ 805 (Fed. Cir. 1986); *In re Baxter*, 656 F.2d 679, 686, 210 USPQ 795, 803 (CCPA 1981); *Ex parte Davis*, 80 USPQ 448, 450 (*Bd. App. 1948*) ('comprising' leaves 'the claim open for the inclusion of unspecified ingredients even in major amounts').

Sayre *et al.* taught feed pellets comprising algae expressing recombinant WSSV VP28, VP26, VP24 and/or VP19 proteins for use in feeding crustacean shrimps. The shrimps fed with the algae expressing the WSSV VP proteins are protected from WSSV infection. See Example 5 and column 12. The algae used are *Chlorella* species or *Chlamydomonas* species. See columns

8-12. The recombinantly produced prior art protein or peptide is at least semi-purified since it does not contain other antigens of White Spot Syndrome Virus. Since the prior art prior art one or more recombinant proteins, VP28, VP24, VP26, or VP19 are the same as the Applicants', the capacity to block viral receptors needed for WSSV infection in one or more cells of the animal is viewed as the intrinsic property inseparable from the prior art one or more recombinant proteins or peptides VP28, VP24, VP26, or VP19.

Claims 17-26, 32 and 33 are anticipated by Sayre *et al.*

Rejection(s) under 35 U.S.C. § 103

25) The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth In *Graham v. John Deere Co.*, 148 USPQ 459, that are applied for establishing a background for determining obviousness under 35 U.S.C. § 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or unobviousness.

26) Claim 34 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Kyle *et al.* (US 2004/0047881 A1, of record) or Sayre *et al.* (US 7,410,637, filed 6/20/01) as applied to claim 20 above, and further in view of Nakamura *et al.* (JP 2000354490 A, abstract, of record).

The references of Kyle *et al.* or Sayre *et al.* are applied in this rejection because these qualify as prior art under subsection (e) of 35 U.S.C § 102 and accordingly are not disqualified under U.S.C 103(a).

The teachings of Kyle *et al.* (1998) or Sayre *et al.* are described above which do not expressly teach that the *Chlorella* strain they used is *Chlorella vulgaris*.

However, it was well known in the art at the time of the invention that the *Chlorella* strain routinely used as a host cell to express a protein or a peptide is *Chlorella vulgaris*. For

example, Nakamura *et al.* taught the routine use of *Chlorella vulgaris* as a host cell for recombinant expression of a protein or a peptide. See abstract.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to use Nakamura's *Chlorella vulgaris* strain in place of Kyle's or Sayre's generically recited *Chlorella* strain to produce the instant invention with a reasonable expectation of success. Substitution of one art-known *Chlorella* strain with another, alternative, art-known strain of *Chlorella* strain such as Nakamura's *Chlorella vulgaris* strain for the same purpose of expressing a protein or peptide was well within the realm of routine experimentation, would have been obvious to one of ordinary skill in the art, and would have brought about similar predictable results.

Claim 34 is *prima facie* obvious over the prior art of record.

Remarks

27) Claims 17-26 and 32-34 stand rejected.

28) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. The Fax number for submission of amendments, responses and/or papers is (571) 273-8300, which receives transmissions 24 hours a day and 7 days a week.

29) Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.Mov>. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (in USA or CANADA) or 571-272-1000.

30) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Robert Mondesi, can be reached on (571) 272-0956.

/S. Devi/
Primary Examiner
AU 1645

January, 2010